

Report to Congress on Information Technology as request in Sec. 1125 the Food and
Drug Administration Safety and Innovation Act (FDASIA), P.L. 112-144

Food and Drug Administration

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Introduction

The Food and Drug Administration Safety and Innovation Act (FDASIA) section 1125 of P.L. 112-144 contains the following mandate:

SEC. 1125. INFORMATION TECHNOLOGY.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Service shall— (1) report to Congress on— (A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures; (B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration; (C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and (D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and (2) develop—(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and (B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

This report has been prepared by the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), as required by FDASIA section 1125.

Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. Section 1125 of FDASIA focuses on Information Technology.

As outlined in Section 1125 of FDASIA, HHS is required to report to Congress on:

1. The milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;
2. Efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;
3. The ways in which the Food and Drug Administration uses the plan described in subparagraph (1) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and
4. The extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology.

Furthermore HHS shall develop:

- A. A documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and
- B. A skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

FDA Actions

FDA provides the following updates as requested for each item requested in the Section 1125 of the Food and Drug Administration Safety and Innovation Act.

1. The milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

The new Food and Drug Administration (FDA) Information Management (IM) Strategic Plan version 1.0 was initially endorsed by the FDA Management Board on June 11, 2012, and a copy was provided to the Government Accountability Office (GAO) in July 2012. In November 2012, FDA officially released and published the Information Management Strategic Plan version 1.1: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm324359.htm.>

During the time this document had been under development, the Office of Information Management (OIM) within FDA, reached out to many sources for feedback. In building this plan, careful attention was paid to the FDA Strategic Priorities, the Health and Human Services (HHS) Strategic Plan and the HHS Office of Management and Budget (OMB) Information Technology (IT) Strategic Plans, as well as numerous other FDA, GAO, HHS, and OMB documents. The FDA IM Strategic Plan sets the path forward for modernization of the IT Infrastructure. Its priorities include strengthening real-time connectivity and access to key data and information. This is essential for daily FDA operations and for our connections to the public we serve and to our many partners outside of the agency who depend on FDA for the execution of their own public health missions. The Strategic Plan also focuses on the availability and usability of data essential to the speed and efficiency of decision-making at FDA. The intent of this goal is to facilitate a learning and knowledge network that will enable FDA to assess the potential risks of regulated products on a scale that routinely handles global sources and large volumes of data.

2. Efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

FDA provided an updated IT systems inventory to GAO in June 2012. Following this submission, efforts continued to validate and maintain an inventory of IT systems. The Enterprise Architecture (EA) team worked with the personnel responsible for developing and managing the systems within FDA to validate the system inventory information. These activities included conducting numerous working sessions with the personnel to walk through the information that is currently contained within the inventory for validation and obtaining any information that was missing. These detailed working sessions occurred between June and October of 2012 and substantially increased the quantity and quality of data that FDA possesses about its

IT systems. This action directly resulted in FDA's HHS EA Repository completion rate moving from 65% to 90% complete. The systems inventory is a living document, with the process for its maintenance managed by FDA's EA program.

New governance processes have been implemented that capture and maintain system inventory information across the IT lifecycle to ensure that this inventory is current and managed through each project/system milestone. These processes have oversight provided by CIO Council (CIOC) and the committees created by CIOC. These committees are the Engineering Review Board (ERB) and the Operations Review Board (ORB). CIOC was formed July 2013; the supporting Engineering Review Board (ERB) and Operations Review Board (ORB) boards were designated in August 2013 and charters are being developed. CIOC and its Boards are utilizing a set of integrated "beginning to end" processes that standardize the review, evaluation, prioritization, funding, and implementation of IT and services. CIOC includes participation of recently designated Associate Deputy Chief Information Officers (ADCIO's) from each major Center/Office of FDA along with the Chief Financial Officer (CFO), Chief Information Officer (CIO) for the Agency, Chief Health Information Officer (CHIO), and Human Resources Officer. This membership ensures that Agency level priorities and Center/Office specific priorities receive balanced oversight and provides a forum for cross Agency collaboration.

IT Governance, as executed through CIOC and its committees process, creates and validates strategic alignment of investments with FDA's mission objectives through organizational processes and leadership participation. IT Governance includes creating investment requests, performing business, technology, and architecture reviews, performing strategic and workload planning, including capacity and demand management, and prioritizing how FDA IT performs work. As IT requests are submitted for review, Enterprise Architects, under the guidance of the ERB, evaluate the requests and perform architecture reviews. The Architects will leverage the information contained within our existing architecture (which includes the system inventory) to develop a recommendation to FDA on whether there are existing investments that can already provide the capability that is being requested. If however the request is for a new system or modification to a system, and an existing capability cannot be leveraged, inventory information is collected at this time to ensure the inventory is updated to reflect the information that is available.

Additionally, FDA in July, 2013, formed a Strategic Portfolio Management to utilize the systems inventory information to continually assess FDA capabilities, to determine if there are legacy applications that can be retired, to determine if there are capabilities that are no longer needed because they have been superseded by new capabilities, or to identify opportunities for technology consolidation and/or modernization.

FDA is required to adhere to the HHS requirements for maintaining a systems inventory and utilize the HHS Enterprise Architecture Repository (HEAR) to maintain the inventory. The HHS requirements continue to evolve and grow. Therefore, while the inventory represents a snapshot of what has been approved, the

inventory is being updated continually throughout the normal systems life cycle process. FDA does not implement systems into the production environment that have not been formally approved through the Governance processes.

3. The ways in which the Food and Drug Administration uses the plan described in subparagraph (1) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities;

Following the public release of the IM Strategic Plan version 1.1, a Strategic Management Initiative was immediately initiated. This initiative began with identifying and assigning executive sponsors for each of nearly 40 strategic activities within the IM Strategic Plan. The executive sponsors have been meeting on a bi-weekly basis to establish a definition and scope for each strategic activity. The initial phase of defining each Strategic Activity and its scope is nearing completion, with the result that the number of defined activities has expanded to about 50. However, this process is ongoing and will continue to evolve as the needs of the Agency evolve, along with the expanding opportunities enabled by advances in technology. Once a specific Strategic Activity is defined and has consensus on scope, the executive sponsor focuses on establishing current state and target state for that activity, and defines roadmaps and metrics to measure progress. Based on an initial assessment of the IM Strategic Plan, FDA is hopeful that many of the modernization and enhancement initiatives that are already underway will align with the roadmaps. If the current initiatives do not align with the roadmaps, FDA will need to determine if the initiatives need to be modified and will look at prioritizing and applying resources to initiatives that are not already started. This prioritization and resource assignment is targeted for incorporation in the execution of the FY14 and FY15 budgets. Implementation of the IM Strategic Plan has already started and uses a continuous evolutionary process. FDA will track the strategic initiatives and metrics to monitor progress and continually reassess goals and performance, which will lead to further revisions and updates to the IM Strategic plan. FDA intends to publish annual updates and to use this IM Strategic Plan as a living document that guides our efforts.

Furthermore, the EA and Capital Planning and Investment Control (CPIC) teams have leveraged the IM Strategic Plan while performing assessments on the FDA investment portfolio. The EA team assessed the existing capabilities in the portfolio, performed a deeper dive analysis and cataloged the capabilities that exist, identified redundancies and capabilities that are no longer needed, and identified the capability gaps that exist between the strategic plan and the existing architecture. As a result of this analysis, the conceptual target architecture has been developed to support the mission of FDA and continue the IT transformation at FDA. The CPIC team conducted an assessment to evaluate the portfolio balance and investment performance. Both teams are now working with the investment review boards within the agency to make appropriate decisions that are aligned with the strategic plan and target architecture as they evaluate their investments and identify priorities for system development efforts.

4. The extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology.

Outlined below are the GAO recommendations for Executive Action and the extent that FDA has fulfilled or is implementing these recommendations:

1. *Take immediate steps to identify all of FDA's IT systems and develop an inventory that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the agency's IT investment management process.*

FDA provided an updated IT systems inventory to GAO in June 2012. Following this submission, efforts continued to validate and maintain an inventory of IT systems. The EA team worked with the personnel responsible for developing and managing the systems within FDA to validate the system inventory information. These activities included conducting numerous working sessions with the personnel to walk through the information that is currently contained within the inventory for validation and obtaining any information that was missing. These detailed working sessions occurred June through October 2012. The systems inventory is a living document, with the process for its maintenance managed by FDA's EA program.

Processes have been implemented to capture and maintain the system inventory information throughout the lifecycle of the system. FDA implemented/established the ITIM, which is a set of processes that standardize the review, evaluation, prioritization, funding, and implementation of IT and services. IT Governance, as executed through the ITIM process, creates and validates strategic alignment of investments with FDA's mission objectives through organizational processes and leadership participation. IT Governance includes creating investment requests, performing business, technology, and architecture reviews, performing strategic and workload planning, including capacity and demand management, and prioritizing how FDA IT performs work. As IT requests are submitted for review, the EA team evaluates the request and performs an architecture review. The Architects will leverage the information contained within our existing architecture (which includes the system inventory) to develop a recommendation to FDA on whether there are existing investments that can already provide the capability that is being requested. If however, the request is for a new system or modification to a system and an existing capability cannot be leveraged, inventory information is collected at this time to ensure the inventory is updated to reflect the information that is available at the time of the request.

Additionally, the Architects utilize the systems inventory information to continually assess FDA capabilities, to determine if there are legacy applications

that can be retired, to determine if there are capabilities that are no longer needed because they have been superseded by new capabilities, or to identify opportunities for technology consolidation and/or modernization.

FDA is required to adhere to HHS requirements for maintaining a systems inventory and utilize the HHS Enterprise Architecture Repository (HEAR) to maintain the inventory. HHS requirements continue to evolve and grow. Therefore, while the inventory represents a snapshot of what has been approved, the inventory is being updated continually throughout the normal systems life cycle process. FDA does not implement systems into the production environment that have not been formally approved through the ITIM process.

2. *In completing the assessment of Mission Accomplishments and Regulatory Compliance Services (MARCS), develop an Integrated Master Schedule (IMS) that:*
 - a. *identifies which legacy systems will be replaced and when;*
 - b. *identifies all current and future tasks to be performed by contractors and FDA; and*
 - c. *defines and incorporates information reflecting resources and critical dependencies.*

As a result of the Mission Accomplishment and Regulatory Compliance Services (MARCS) assessment, an Office of Regulatory Affairs (ORA)/ OIM Business and Technology Rethink effort was launched and completed at the end of November 2012. A large contingent of ORA staff, as well as representatives from OIM and the Centers, carefully examined and mapped ORA business processes and conducted a Strengths, Weaknesses, Opportunities and Threats analysis.

A framework of business and IT changes that could be made to improve ORA processes was identified. The ORA/OIM Business and Technology Rethink team have performed a preliminary assessment of existing service capabilities and new capabilities against the Rethink framework. Agency leadership has been evaluating the deliverables that were produced by the ORA/OIM Business and Technology Rethink effort and has recently approved to resume this fiscal year work that is in alignment with the strategic shifts needed within the Office of Global Regulatory Operations.

Due to the fact that there was an assessment and then a subsequent ORA/OIM Business and Technology Rethink effort, it was not possible to complete an Integrated Master Schedule (IMS) at that time. Now that the decision has been made for work to resume, the project team will be completing the initiation phase and moving into the detailed planning phase of the project management life cycle where an IMS will be created.

Furthermore, a permanent Director for the Division of Systems Management within the OIM organization was selected at the end of October 2012. The new Director of Systems Management has an extensive technical background and extensive experience in program management. Additionally, OIM has established a Program Management Office that is responsible for monitoring and reporting on program and project progress, providing mentoring and guidance to program and project managers, and ensuring program and project management principles and best practices are being followed and executed properly.

3. *Monitor progress of MARCS against the IMS.*

FDA will have an integrated master schedule (IMS) for the Mission Accomplishment and Regulatory Compliance Services (MARCS) program by November 30, 2013. Once the IMS is created, the IMS will be base-lined and progress will be monitored and measured against it.

4. *Assess information-sharing needs and capabilities of Center for Food Safety and Applied Nutrition (CFSAN) to identify potential areas of improvements needed to achieve more efficient information sharing among databases and develop a plan for implementing these improvements.*

A deep dive architectural assessment of the Office of Foods and Veterinary Medicine, which encompasses CFSAN and the Center for Veterinary Medicine, will be performed this fiscal year to assess information sharing needs and capabilities and identify areas of improvement for efficient information sharing across the agency.

Furthermore HHS shall develop:

A. A documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management;

The EA program management plan (PMP) was finalized in February 2013. The EA PMP outlines the key EA Program components, EA development initiatives, and ongoing EA operational activities necessary to accelerate FDA's implementation of a fully functional EA organization based on a standardized set of business capabilities. A high-level roadmap is included, which depicts the steps to stand up the EA organization. The establishment of this federated organization will provide FDA with the ability to meet mandates from HHS and OMB, improve business transformation, drive technology standardization, and translate business strategy into actionable plans.

B. A skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

FDA has conducted several focused exercises to capture skills from IT professionals within the OIM organization, performed a gap analysis, and established training plans for modernizing and transforming IT Professionals skills sets over the last few years. However, this activity is a living process that must continually occur to ensure IT professionals are keeping pace with the evolution of technology and are able to provide innovative tools in support of the expanding mission of FDA. Therefore, one of the goals identified in the IM Strategic Plan is to develop a leadership pipeline of highly engaged, qualified, and customer-centric employees that are experts in technologies and in the business and scientific domains in which they serve. In order to meet this goal, FDA will complete a needs assessment across the IT organization by the end of FY 2013. In FY 2014, FDA will update training and recruiting plans to ensure the IT organization addresses the needs that have been identified and collected. Furthermore, a skills inventory and gap analysis will be performed. Training and recruitment plans will be continuously reviewed and updated after the completion of each activity referenced above.

Additionally, FDA is looking to leverage a tool that is already being used within the Agency to ensure these activities do actually become a living process. The tools that are being considered are SharePoint and Profiles Research Networking Software (RNS).

By employing one of these powerful tools to serve as the skills inventory repository, the skills inventory can be easily maintained and the data can be quickly searched and analyzed. Skill gaps can be identified and individual development plans established and implemented rapidly.